

**REMARKS**

Claims 1 - 11 were previously canceled. Claim 25 has been cancelled. Thus, claims 12-24 remain pending in the present application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are in condition for allowance.

Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite as failing to particularly point out and distinctly claim the subject matter of the invention. (See 2/7/11 Office Action, p. 2). As claim 25 has been cancelled, it is respectfully submitted that this rejection is moot.

Claims 12 - 25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,766,174 to Perry in view of U.S. Patent No. 5,041,115 to Frigg et al. (hereinafter "Frigg") in further view of U.S. Patent No. 6,547,791 to Buhren et al. (hereinafter "Buhren") in further view of U.S. Patent No. 6,270,499 to Leu et al. (hereinafter "Leu"). (See 2/7/11 Office Action, p. 3).

Claim 12 recites an intramedullary nail comprising "an elongated nail body having a proximal end, a distal end for insertion into the medullary canal, a central axis and a total length L; three locking sections along the length of the nail body between the proximal and distal ends, each locking section including a through-hole for receiving a locking screw, the three locking sections including a proximal locking section, a medial isthmus locking section and a distal locking section; and two distinct intermediate sections separating the three locking sections...wherein the locking section nearest the proximal end comprises an elongated through-hole; and *wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole.*"

The Examiner acknowledges that Perry, Frigg, and Buhren do not disclose an isthmus locking section including two through holes arranged at a relative angle A as recited. (See 2/7/11 Office Action, p. 7). The Examiner attempts to cure this deficiency with Leu. Initially, it is respectfully submitted that the Examiner's assertion that the bores 7 and the anteroposterior bore 29 are disposed on a portion of the intramedullary nail 1 of Leu analogous to the recited isthmus locking section is misplaced. As would be clear to those skilled in the art, an isthmus locking section of an intramedullary nail is a portion of the nail which, when implanted to a desired location, is located within the isthmus of the bone - i.e., the thin shaft extending between the enlarged ends of the bone. Those skilled in the art understand that fractures in this area require different treatment than those on the trochanteric area and that portions of a nail extending within the isthmus will be subjected to different forces and, therefore, have specific structural requirements that distinguish isthmian portions of nails from the ends which reside outside the isthmus. In its entirety, Leu neither states nor suggests that the bores 7, 29 are located at the isthmus of the bone. In contrast, as illustrated in Fig. 1 and the annotated Fig. 1 provided by the Examiner, the bores 7, 29 are within the thickened trochanter at the proximal end of the bone - outside of the isthmus. Specifically, Leu states that the bores 7 are "in the area of the proximal end 3" of the nail. (See Leu, col. 3, line 57). As the bore 29 is between the bores 7, it is also in the area of the proximal end 3. Furthermore, Leu states that a "preferred refinement" of the invention consists of a bore running across the central axis of the nail "in the area of the proximal end" to lock the nail in position. (*Id.*, col. 2, lines 63 - 67).

The intramedullary nail 1 of Leu is described as functioning as an intramedullary angle plate providing increased contact between the implant and bone to permit reconstruction of the head of the tibia even if that tibia is osteoporitic. (See *Id.*, col. 2, ll. 40 - 53). Specifically, the head 10 of the nail at the proximal end is required to lock the nail in position even where bone quality is low. Thus, the bores 7 and 29 are provided not in the isthmus, but in the thickened end of the bone to increase bony purchase as the head 10 of the nail 1 provides the load-

bearing element. (See Id., col. 2, ll. 54 - 67). In addition, Leu shows the nail 1 including bores 6 and a threaded bore 8 at the *distal end* of the nail 1 to be disposed near the isthmus of the bone, not for a *medial* locking section. (See Id., Figs. 1, 4, 6). As described in the specification, these bores are located “in the area of the distal end” of the nail. (Id. at col. 2, lines 63 - 67). Thus, it is respectfully submitted that Leu does not disclose or suggest an isthmus locking section and, accordingly, through holes thereof.

Furthermore, even if the bores 7, 29 were considered through holes of an isthmus locking section (which is not conceded), Leu fails to disclose or suggest an isthmus locking section including “a proximal through hole and a distal through hole, the proximal through hole being *arranged at an angle of 90°* relative to the distal through hole,” as recited in claim 12. It is noted that claim 12 recites that the two through holes are arranged at a specific angle of 90°, not a relative angle with respect to each other such as any non-parallel orientation. In contrast, Leu only teaches bores 7 and an anteroposterior bore 29 extending through the intramedullary nail 1 that are arranged in a non-parallel fashion, but includes absolutely no showing or suggestion that any of these bores is perpendicular to any other. (See Leu, col. 3, ll. 57-62; Figs. 1, 4, 6). In its entirety, Leu includes no disclosure with respect to the angles of these bores relative to one another. It is respectfully submitted that no conclusion about the angular relationship between the bores may properly be drawn from an Examination of the drawings alone and that Leu does not cure the deficiencies of Perry, Frigg and Buhren.

It is respectfully maintained that the Examiner’s assertion that the device of Perry is capable of being modified with any teaching regarding an isthmus locking section having through holes arranged in any configuration other than parallel is also incorrect. The purported isthmus locking section of Perry comprises only bone transfixation holes 34a, 34b formed parallel to one another and no indication is provided in any of the references why this arrangement should be modified, much less modified as claimed. (See Perry, col. 3, ll. 10-19, 33-40; col. 5, ll. 43-53; Figs. 1-6). Perry is incapable of being modified to overcome this

deficiency since the device of Perry is explicitly configured with parallel transfixation holes 32a, 32b, 34a, 34b so that insertion of a locating screw 28 into an indent 59 formed in anvil assembly 26 aligns the guides holes 40a, 40b, 42a, 42b of the alignment tower 24 with respective transfixation holes 32a, 32b, 34a, 34b of the intramedullary nail 20. (*Id.*, col. 3, ll. 33-40; col. 5, l. 40 - col. 6, l. 2; Figs. 1-3). It is therefore respectfully submitted that Perry teaches only one possible configuration of the alignment tower 24 with respect to the intramedullary nail 20 (*i.e.*, the configuration assumed when the locating screw 28 is received in the indent 59). Accordingly, the transfixation holes 34a and 34b of Perry which purportedly correspond to the through holes of the isthmus locking section of claim 12 can be disposed only in the disclosed parallel configuration. A primary focus in Perry is to provide a definitive means for locating the transfixation holes through the proper alignment thereof for the introduction of transfixation screws. Therefore, to provide the transfixation holes 34a and 34b in a non-parallel configuration teaches away from the device disclosed in Perry as the alignment feature with the tower 24 and the side bar 25 is no longer viable. Thus, a non-parallel transfixation hole 34a or 34b would find no utility in the device of Perry since there would be no means for locating the hole within the bone. It is respectfully submitted that Perry is incapable of being modified to overcome this limitation.

It is therefore respectfully submitted that Perry, Frigg, Buhren, and Leu, taken alone or in combination, do not disclose or suggest “wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole,” as recited in claim 12 and that claim 12 is in condition for allowance. Because claims 13 - 22 depend from and include the limitations of claim 12, it is respectfully submitted that these claims are also allowable.

Claim 23 recites limitations substantially similar to claim 12, including an intramedullary nail “wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to

the distal through hole.” It is therefore respectfully submitted that claim 23 is also allowable over Perry, Frigg, Buhren, and Leu, taken alone or in combination, for substantially the same reasons noted above with respect to claim 12. Because claim 24 depends from and includes the limitations of claim 23, it is respectfully submitted that this claim is also allowable.

In light of the foregoing, Applicants respectfully submit that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated:

5/3/11

By: 

Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP  
150 Broadway, Suite 702  
New York, N.Y. 10038  
(212) 619-6000 (telephone)  
(212) 619-0276 (facsimile)